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EXAMINER

GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/12/2003

124

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,951

Applicant(s)

DENNIS ET AL.

Examiner

Jeanine A Goldberg

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 34-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8, 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

1. This action is in response to the papers filed November 29, 2002. Currently, claims 1-38 are pending. Claims 34-38 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election without traverse of Group I, Claims 1-33 in Paper No. 13 is acknowledged.

The requirement is still deemed proper and is therefore made FINAL.

Sequence Rules

3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

The specification contains several sequences which are not identified by SEQ ID NO:.. For example, page 15, 18, 19 contains primers which have not been identified by SEQ ID NO:.. Appropriate correction is required.

Drawings

4. The drawings are objected to by the examiner. Figure 2 contains sequences which are not identified by SEQ ID NO:.. Neither the figure nor the brief description of the drawings contains an identifier. Appropriate correction is required.
5. Figure 1, 3, 4 has multiple drawings. Each of these have not been described in the brief description of the drawings. For example, Figure 1B has not been described.
6. Figure 3 states that the polymorphic site is shown in red letters, however, the figures do not contain any red letters. Clarification is requested.

Specification

7. The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.
8. The title of the invention is not descriptive of the elected invention. A new title is required that is clearly indicative of the invention to which the claims are directed.

Claim Objections

9. Claim 9 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper

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dependent form, or rewrite the claim(s) in independent form. Claim 9 and Claim 2 are essentially the same claim. Claim 2 requires a "difference in DNA methylation" whereas Claim 9 requires "DNA methylation difference." It is unclear how Claim 9 further limits Claim 2.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 21-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 21-23 are indefinite because the claims are dependant upon Claim 17 which is dependant upon Claim 15 which requires measuring the concentration of fetal DNA in maternal plasma or serum. It is unclear how imprinting which is relative to methylation will be ascertained by concentration of fetal DNA. It appears as though the claims may be improperly dependant. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

11. Claims 1, 3-5, 8, 14-20, 24, 27, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lo et al. (WO 98/39474, September 11, 1998) and rejected under 35 U.S.C. 102(e) as being anticipated by Lo et al. (US Pat. 6,258,540, July 10, 2001).

It is noted that the disclosure of both of the documents is identical. The page numbers refers to the WO document.

The instant specification defines "epigenetic differences" as "any molecular or structural difference other than the primary nucleotide sequence" (page 10, lines 4-6).

Lo et al. (herein referred to as Lo-WO) teaches a method of non-invasive prenatal diagnosis including sex determination and detection of pre-eclampsia in a mother. The prenatal method of Lo-WO differentiates DNA species from a mother and a fetus in maternal serum or plasma by determining epigenetic differences between the DNA species from the mother and the fetus (limitations of Claim 1). The epigenetic differences taught to be detectable in maternal serum and plasma includes detection of Y chromosome specific nucleic acids for sex determination (page 3), chromosomal aneuploidies such as Down's Syndrome (page 5), and elevated concentration of fetal DNA in pre-eclampsia (page 5-6). In Example 1, Lo-WO provides an analysis of fetal DNA for sex determination (page 6). Maternal peripheral blood was collected,

centrifuged and the plasma and serum were removed (page 7)(limitations of Claim 3). Lo-WO teaches performing a PCR reaction with Y-specific primers. Lo-WO teaches that ~~non~~^{of} of the 13 women bearing female fetuses and none of the non-pregnant female controls resulted in a positive Y signal when either plasma, serum or cellular DNA was amplified, indicating the accuracy of the technique (page 9)(limitations of claim 4, 5, 14, 24, 27, 33). Example 2 demonstrates a quantitative analysis of fetal DNA in maternal serum in aneuploid pregnancies (page 14). Real time quantitative SYR PCR was performed on serum DNA extracted from women bearing aneuploid and normal fetuses (page 14) and for pre-eclamptic and control patients (page 22). The results demonstrated that the concentration of fetal DNA in maternal serum is elevated in aneuploid pregnancies (page 14) and in pre-eclamptic compared with non-pre-eclamptic pregnancies (page 22)(limitations of claims 8, 15-20). Therefore, since Lo-WO teaches every limitation of the claims, Lo-WO anticipates the claimed invention.

12. Claims 1, 3-4, 6, 27, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Lo et al (The Lancet, Vol. 351, pages 1329-1330, May 1998).

Lo et al. (herein referred to as Lo-Lancet) teaches the presence of donor-specific DNA in plasma of kidney and liver-transplant recipients. Lo-Lancet teaches venous blood was collected from individuals who had a transplant of an organ. The blood was centrifuged to obtain plasma, amplified using Y-specific PCR and analyzed (limitations of claims 3-4). The results of the study demonstrated that in 100% of the male donors and female recipients, an Y specific sequence was found (page 1239, col.2)(limitations

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of claims 1, 6, 27, 33). The method of Lo-Lancet therefore is successful in differentiating DNA species from two individuals, namely an organ donor and an organ recipient, by determining the presence of Y specific sequences, an epigenetic difference.

13. Claims 1-2, 4-5, 9-11, 13, 21-23, 27-29, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuboto et al (Nature Genetics, Vol. 16, pages 16-17, May 1997).

The rejection of Claims 21-23 are appropriate in the event that the claims are made dependant upon Claim 14, for example, rather than dependant upon concentration of fetal DNA.

Kuboto et al. (herein referred to as Kuboto) teaches a methylation-specific PCR method which simplifies imprinting analysis. Kuboto teaches that genomic imprinting plays an important role in Prader-Willi syndrome (PWS) and Angelman syndrome (AS). There is differential methylation between the maternal homologue and the paternal homologue such that the maternal homologue is methylated and inactive while the paternal homologue is unmethylated and transcriptionally active (page 16, col. 1). Kuboto teaches a methylation-specific PCR assay for the detection of PWS and AS using DNA treated with sodium bisulphate, which converts cytosine to uracil except when cytosine is methylated (page 16, col. 1)(limitations of claims 10). After treatment of the genomic DNA with bisulfite CpG dinucleotides are methylated in over 96% of the maternal chromosome, whereas none are methylated on the paternal chromosome.

PCR primers were designed to amplify the region. Normal individuals showed both a 174-bp PCR product and a 100-b PCR product; PWS patients showed only the 174-bp product; and AS patients only showed 100-bp PCR product (limitations of claims 1, 2, 9, 11, 13, 27-29, 33). Thus, Kuboto teaches a method of differentiating DNA species from different individuals in a biological sample, namely blood, amniotic fluid or chorionic villus, by determining epigenetic differences, namely methylation, between the DNA species (page 17, col. 1)(limitations of claims 4, 5). Therefore, since Kuboto teaches every limitation of the claims, Kuboto anticipates the claimed invention.

14. Claims 1, 4, 6-8, 25-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Mangioni et al. (Bone Marrow Transplantation, Vol. 20, pages 969-973, 1997).

Mangioni et al. (herein referred to as Mangioni) teaches a method of monitoring long-term persistence of hemopoietic chimerism following sex-mismatched bone marrow transplantation. Mangioni teaches that the detection of male cells was positive in all but two of the 52 samples. Mixed chimerism was found in all patients. Mangioni teaches that many methods have been used to analyze chimerism after bone marrow transplantation (BMT) to evaluate engraftment or rejection, to detect minimal residual disease or recurrence of leukemia and to clarify the clinical significance of the presence of mixtures of hemopoietic cells of donor and recipient origins. Mangioni teaches staining cells and extracting DNA. Mangioni teaches performing PCR amplification of the Y chromosome-specific DYS14 sequence. Mangioni teaches performing an electrophoresis and a Southern blot to detect the nucleic acid, such that concentrations

are relatively determined (limitations of Claim 8, 25-26). As seen in Figure 2, residual male cells in male recipients grafted from female donors were revealed by dot blot technique (limitations of claim 1, 4, 6-7, 27). Thus, Mangioni detects and differentiates DNA species originating from donor and recipients in a biological sample by determining the presence of a Y chromosome specific DYS14 sequence. Thus since Mangioni teaches every limitation of the claims, Mangioni anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kuboto et al (Nature Genetics, Vol. 16, pages 16-17, May 1997) in view of Herman et al. (PNAS, Vol. 93, pages 9821-9826, September 1996).

Kuboto et al. (herein referred to as Kuboto) teaches a methylation-specific PCR method which simplifies imprinting analysis. Kuboto teaches that genomic imprinting plays an important role in Prader-Willi syndrome (PWS) and Angelman syndrome (AS). There is differential methylation between the maternal homologue and the paternal homologue such that the maternal homologue is methylated and inactive while the paternal homologue is unmethylated and transcriptionally active (page 16, col. 1). Kuboto teaches a methylation-specific PCR assay for the detection of PWS and AS using DNA treated with sodium bisulphate, which converts cytosine to uracil except when cytosine is methylated (page 16, col. 1)(limitations of claims 10). After treatment of the genomic DNA with bisulfite CpG dinucleotides are methylated in over 96% of the maternal chromosome, whereas none are methylated on the paternal chromosome. PCR primers were designed to amplify the region. Normal individuals showed both a 174-bp PCR product and a 100-bp PCR product; PWS patients showed only the 174-bp product; and AS patients only showed 100-bp PCR product (limitations of claims 1, 2, 9, 11, 13, 27-29, 33). Thus, Kuboto teaches a method of differentiating DNA species from different individuals in a biological sample, namely blood, amniotic fluid or chorionic villus, by determining epigenetic differences, namely methylation, between the DNA species (page 17, col. 1)(limitations of claims 4, 5).

Kuboto does not specifically teach sequencing DNA to detect a DNA methylation difference.

However, Herman teaches that following chemical modification of cytosine to uracil by bisulfite treatment, the altered DNA may be amplified and sequenced to provide detailed information within the amplified region of the methylation status of all CpG sites. Herman specifically states that "the only technique that can provide more direct analysis than MSP for most CpG sites within a defined region is genomic sequencing" (page 9825, col. 2).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have sequenced the nucleic acid of the small nuclear ribonucleoprotein-associated polypeptide, taught by Kuboto to be differentially methylated, to determine the methylation status of the nucleic acid in an individual. The ordinary artisan would have clearly recognized that the method of sequencing the nucleic acid would have been an equivalent means of determining the methylation status of the region. The method of sequencing the entire region provides detailed information within the amplified region of the methylation status of all of the CpG sites. While the method of methylation-specific PCR may have its advantages, sequencing the entire amplified regions provides a very clear detailed analysis of each of the CpG sites within the nucleic acid. Herman states that "the only technique that can provide more direct analysis than MSP for most CpG sites within a defined region is genomic sequencing" (page 9825, col. 2). With this very clear detailed analysis, the ordinary artisan will be able to determine whether certain CpG sites are essential to a specific

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diagnosis. Therefore, depending on the information desired by the ordinary artisan, the ordinary artisan may choose to perform the methylation detection assay using either the methylation specific PCR method or a more detailed sequencing analysis of the entire region.

17. Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuboto et al (Nature Genetics, Vol. 16, pages 16-17, May 1997) in view of Nuovo et al. (PNAS, Vol. 96, No. 22, pages 12754-12759, October 26, 1999).

Kuboto et al. (herein referred to as Kuboto) teaches a methylation-specific PCR method which simplifies imprinting analysis. Kuboto teaches that genomic imprinting plays an important role in Prader-Willi syndrome (PWS) and Angelman syndrome (AS). There is differential methylation between the maternal homologue and the paternal homologue such that the maternal homologue is methylated and inactive while the paternal homologue is unmethylated and transcriptionally active (page 16, col. 1). Kuboto teaches a methylation-specific PCR assay for the detection of PWS and AS using DNA treated with sodium bisulphate, which converts cytosine to uracil except when cytosine is methylated (page 16, col. 1)(limitations of claims 10). After treatment of the genomic DNA with bisulfite CpG dinucleotides are methylated in over 96% of the maternal chromosome, whereas none are methylated on the paternal chromosome. PCR primers were designed to amplify the region. Normal individuals showed both a 174-bp PCR product and a 100-b PCR product; PWS patients showed only the 174-bp product; and AS patients only showed 100-bp PCR product (limitations of claims 1, 2, 9, 11, 13, 27-29, 33). Thus, Kuboto teaches a method of differentiating DNA species from

different individuals in a biological sample, namely blood, amniotic fluid or chorionic villus, by determining epigenetic differences, namely methylation, between the DNA species (page 17, col. 1)(limitations of claims 4, 5).

Kuboto does not specifically teach using methylation specific polymerase chain reaction (PCR) in situ to detect methylation.

However, Nuovo et al. (herein referred to as Nuovo) teaches in situ detection of methylation using an in situ methylation-specific PCR. Nuovo teaches that hypermethylation is associated with loss of expression of one copy in the normal settings of inactivation of the female X chromosome and the silenced alleles for paternally imprinted gene (page 12754, col. 1). Nuovo teaches that the methods of genomic sequence to assess cytosine methylation does cannot easily address critical issues such as the precise timing of DNA methylation changes in specific cell types during embryonic development (page 12754, col. 1). Nuovo teaches a method of using MSP-ISH (methylation-specific PCR in situ) for tracing the evolution of cell populations harboring hypermethylation associated inactivation (page 12754, col. 2).

Therefore, it would have been prima facie obvious to one of ordinary skill at the time the invention was made to have modified and improved the method of Kuboto which analyzes DNA from women who are pregnant to detect the presence of PWS and AS. The ordinary artisan would have recognized based upon the teachings of Nuovo that analysis of cells provides the increased benefit of tracing the evolution of cell populations which contain methylation associated inactivation. By modifying the method of Kuboto to analyze cells will provide additional information regarding the

precise timing of DNA methylation and change in specific cell types during embryonic development as suggested by Nuovo. In order to further analyze and study the inactivation of the female X chromosome and imprinting, the ordinary artisan would be motivated to determine the temporal methylation to further study and analyze the PWS and AS disorders.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

18. Claims 1, 3-5, 8, 14-20, 24, 27, 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-7, 12-25 of U.S. Patent No. 6,258,540.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d

1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentable distinct from each other because Claim 1, 3-5, 8, 14-20, 24, 27, 33 of the instant application is generic to all that is recited in Claim 1-7, 12-25 of U.S. Patent No. 6,258,540. That is, Claim 1-7, 12-25 of 6,258,540 falls entirely within the scope of Claim 1, 3-5, 8, 14-20, 24, 27, 33, or in other words, Claim 1, 3-5, 8, 14-20, 24, 27, 33 are anticipated by Claim 1-7, 12-25 of 6,258,540. Here, claim 1 of U.S. Patent No. 6,258,540 recites a method for detecting paternally inherited nucleic acids of fetal origin performed on maternal serum or plasma by detecting the presence of a paternally inherited nucleic acid.


Conclusion

19. No claims allowable over the art.

20. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.


Jeanine Goldberg
February 6, 2003